

### **REMARKS/ARGUMENTS**

Claims 54-69 are currently pending in this application. Claims 54-63 have been canceled. Claim 64 has been amended and support can be found, for example, at page 22 lines 24-27. New claims 70-77 have been added.

With respect to all claims, Applicants have not dedicated, disclaimed, or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants reserve the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional applications.

#### **New claims**

Applicants point out that new claim 70 recites a “bispecific antibody comprising two heteromeric polypeptides and two light chains”. Claims 71-74 and 76 depend from claim 70. Claim 75 depends from claim 74 and claim 77 depends from 73.

Support for the new claims can be found in the specification and claims as originally filed. Support for claim 70 can be found, for example, in the Abstract, Figure 1C, at page 13 lines 15-21, and at page 22 lines 24-27. The entry of new claims 70-77 is respectfully requested.

#### **Double patenting rejections**

Applicants request that the Examiner hold these rejections in abeyance until notice of allowable subject matter.

#### **Rejections under 35 U.S.C. §102**

Claims 54 and 56 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by *de Kruif*, et al. (1996) J. Biol. Chem. 271(13): 7630-7634, 1996 (hereinafter referred to as “de Kruif-A”) as evidenced by *de Kruif*, et al. (1995) J. Mol. Biol. 248: 97-105 (hereinafter referred to as “de Kruif-B”). Claims 54 and 56 have been canceled rendering this rejection moot. Withdrawal is respectfully requested.

#### **Rejections under 35 U.S.C. §103**

Claims 54, 55, 58-61 and 63 stand rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over *Carter*, et al. WO 96/27011 published September 6, 1996; cited in IDS (hereinafter referred to as “Carter-B”) in view of de Kruif-A and further in view of de Kruif-B. Claims 54, 55, 58-61, and 63 have been canceled rendering this rejection moot. Withdrawal is respectfully requested.

Claims 54, 56-60 and 63 stand rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over Hu et al. (1996) Cancer Research, 56:3053-3061; cited in IDS (hereinafter referred

to as “Hu”) in view of de Kruif-A and further in view of de Kruif-B. Claims 54, 56, 57-60, and 63 have been canceled rendering this rejection moot. Withdrawal is respectfully requested.

**Rejections under 35 U.S.C. §112, first paragraph – Written description**

Claims 64-69 remain rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner argues that bispecific antibodies “comprising common light chains where the definition of common light chains is one where the sequences are not identical constitutes new matter.” (page 6 of the April 10, 2008 Office Action). Applicants traverse the rejection for the reasons of record and submit that upon application of the proper legal standard for written description, claims 64-69 comply with the written description requirement. M.P.E.P. §2163 I. provides that to

satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.

As previously argued by Applicants, support for claims 64-69 can be found at page 22, line 18 to page 23, line 5. In addition, Example 4 and Figure 4 provide additional support for claim 64-69. As described in Example 4, Figure 4 is a comparison of V<sub>L</sub> sequences of eight different antibodies disclosed in the specification and shows that some light chains differ in their amino acid sequence outside the antigen binding CDR regions (page 97, lines 14-30). As a result, Applicants respectfully submit that the instant specification provides explicit support for claims 64-69.

The Examiner asserts that

the passages referred to by applicants, are passages describing processes for identification of useful light chains to be used as common light chain of a bispecific antibody. The passages cited by applicant do not define the term “common light chain” to include light chains present in a bispecific antibody where the two light chains are different in amino acid sequence. Therefore, the passages cited by applicant do not provide support for the claimed invention. [emphasis added] (pages 4-5 of the January 22, 2009 Office Action)

The Examiner appears to argue that the previously cited passages do not provide support for claims 64-69 because they “describe processes for identification of useful light chains to be used as common light chain of a bispecific antibody”. Applicants submit that this is not a proper basis for the rejection in light of the legal standard. The previously cited passages (page 22, line 18 to page 23, line 5) provide explicit support for useful light chains that differ in their amino acid sequence outside the CDR regions. Example 4 and Figure 4 provide specific examples of such useful, non-identical light chains. Therefore, Applicants submit that a person of ordinary skill in the art would reasonably conclude that the Applicants’ had possession of a bispecific antibody formed from two such useful light chains.

Based on the foregoing, Applicants respectfully submit that the present specification provides adequate written description for claim 64 and all claims depending therefrom. As such, no new matter has been introduced and the rejection should be withdrawn.

**CONCLUSION**

In light of the above amendments, Applicants believe that this application is now in condition for immediate allowance and respectfully request that the case be passed to issue.

Please charge any fees that might become applicable, including any fees for extension of time, or credit overpayment to Deposit Account No. 50-4634, referencing Attorney's Docket No. GNE-0215.006 US R2C1(123851-181381).

Respectfully submitted,  
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